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Examiner C. Azpuru
United States Patent and Trademark Office

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Boehringer Ingelheim Corporation

December 17, 2002

USSN 09/975,418; Atty. Docket No. 1/1149

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Dear Examiner Azpuru:

With regard to the above-referenced patent application, enclosed are the following documents:

1. Response to Restriction Requirement (5 Pages)

If you have any questions regarding the enclosed, please call me at 203/798-4542.

Sincerely,

Philip I. Datlow
Attorney for Applicant(s)

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bechtold-Peters, et al

Appln. No.: 09/975,418 Group Art Unit: 1615

Confirmation No.: 4479 Examiner: C. AZPURU

Filed: 10/11/2001 Attny Docket No.: 1/1149

For: INHALABLE POWDER CONTAINING TIOTROPIUM

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Office Action dated November 27, 2002, in which the Examiner set forth a restriction requirement in four groups as follows:

I. Claims 1-10, drawn to an inhalable powder

II. Claims 11-12, drawn to a method of preparing an inhalable powder

III. Claims 13-14, drawn to a method of treating a disease

IV. Claims 15-17, drawn to an inhalable capsule

Applicants hereby elect Group I, Claims 1-10, with traverse. Applicants believe that this restriction requirement is improper and should be withdrawn for the reasons outlined below, and withdrawal of the restriction is therefore respectfully requested.

In arguing for restriction between Groups I and II, the Examiner specifically argues that "the product as claimed can be made by a materially different process such as a solvent extraction

process." Applicants respectfully disagree with the Examiner's conclusion. The inhalation powder of the present invention comprises tiotropium (which may be in salt form) and a physiologically acceptable excipient consisting of a mixture of a finer particle fraction and a coarser particle fraction. The specification describes that this inhalation powder is obtained by mixing the two excipient fractions and then mixing the resulting excipient mixture with the tiotropium, which is the process claimed in claim 11. See page 6, line 25, to page 8, line 11. Applicants do not believe that the inhalable powder of the present invention can be obtained by a solvent extraction process as argued by the Examiner. The Examiner is respectfully requested to provide a detailed, technical explanation supported by documentary evidence if the Examiner maintains that a solvent extraction process may be used to obtain the inhalable powder of the present invention.

In arguing for restriction between Groups I and III, the Examiner argues that "the process for using the product as claimed can be practiced with another materially different particle drug delivery system." Applicants respectfully disagree with the Examiner's conclusion. The process for using the product "as claimed" (in claims 13-14) is directed to the use of the inhalable powder of Group I.

In arguing for restriction between Groups I and IV, the Examiner argues that the inventions are unrelated and have different modes of operation "in that a capsule contains the bioactive within a surrounding membrane, whereas a powder is impregnated or coated with the bioactive. The

resulting release profiles are therefore quite different." Applicants respectfully disagree with the Examiner's conclusion. First, inventions are only unrelated if they are not connected in design, operation or effect and are not disclosed as capable of use together. See MPEP 806.04 and 808.01. The inhalable powder of Group I and the capsule of Group IV are related inventions and are clearly disclosed as capable of use together – the inhalable powder is prepared and then is inserted into the inhalette capsule which is used to deliver the inhalable powder directly to the lungs of the patient by an inhalation process. Moreover, the examination should be somewhat coextensive since if the inhalable powder of Group I is found to be patentable over the prior art, the inhalette capsule of Group IV should likewise be found patentable over the prior art since it contains the inhalable powder of Group I.

In arguing for restriction between Groups II and III, the Examiner argues that the inventions are unrelated. Applicants respectfully disagree with the Examiner's conclusion. Inventions are only unrelated if they are not connected in design, operation or effect and are not disclosed as capable of use together. See MPEP 806.04 and 808.01. The methods of Groups II and III are related inventions and are clearly disclosed as capable of use together – the inhalable powder is made by the process of Group II and is then used for the treatment of disease as covered by Group III.

In arguing for restriction between Groups II and IV, the Examiner argues that the inventions are unrelated. Applicants respectfully disagree with the Examiner's conclusion. Inventions are only

unrelated if they are not connected in design, operation or effect and are not disclosed as capable of use together. See MPEP 806.04 and 808.01. The method of Group II and the capsule of Group IV are related inventions and are clearly disclosed as capable of use together – the inhalable powder is made by the process of Group II and then the powder is used to make the inhalette capsule of Group IV as discussed above.

In arguing for restriction between Groups III and IV, the Examiner argues that the process of using the product (Group III) can be practiced with another and materially different product such as the inhalable powder. As discussed above, however, the inhalette capsule of Group IV is in fact used to deliver inhalable powder directly to the patient by inhalation.

Moreover, there should not be an undue examination burden in this application since if the inhalable powder of Group I is found to be patentable over the prior art, then Groups II – IV should likewise be found patentable since they are directed either to the preparation or use of the inhalable powder of Group I or to a capsule containing the inhalable powder of Group I.

Applicants also submit that the methods of Groups II and III should, in any case, be rejoined in the examination of the inhalable powder of elected Group I under the USPTO's Rejoinder Practice, as set forth in MPEP 821.04, in the event that the inhalable powder of Group I is found to be patentable. The method claims of Groups II and III all depend from the product claims of Group I

for the definition of the inhalable powder.

In view of the above, Applicants respectfully request that the restriction requirement be withdrawn.

Applicants respectfully submit that this application is now in condition for examination and a prompt examination is respectfully requested.

If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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on December 17, 2002.

Philip I. Datlow